

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)



DP Barcode No.: 418272

File Symbol No.: 90188-R

Decision No.: 487371

PC Code: 028201

Food Use: No

Action Code: R 333

Product Name: Propanil Technical

Date:

December 15, 2014

SUBJECT:

Brune 7. Kutherso 12/15/14 W 116/14 Product Chemistry Review of the Manufacturing Use Product, Propanil Technical

FROM:

Bruce F. Kitchens, Chemist

Chemistry, Inert and Toxicology Assessment Branch/RD (7505P)

Registration Division (7505P)

TO:

RM #, Emily Schmid

Herbicide Branch

Registration Division (7505P)

INTRODUCTION:

The registrant, Pronil LLC, is submitting an application for the registration of the new manufacturing use product, Propanil Technical. The active ingredient in this product is Propanil at a label nominal concentration of 98.5% a.i. This product is intended for use in the manufacture of herbicide end-use products. In addition, the registrant's cover letter dated states that the proposed product is substantially similar in composition to EPA Reg. No. 71085-1 RiceCo Propanil Technical. In support of this request, the registrant has submitted a basic Confidential Statement of Formula (CSF) dated 30 Jan 2014, a draft label, and product chemistry data contained in MRID#s 493099-01 and 493099-02. The Chemistry, Inerts and Toxicology Assessment Branch (CITAB) has been asked to review this submission.

SUMMARY OF FINDINGS:

CITAB has reviewed this submission and reports the following findings:

- 1. This product is produced from an integrated formulation system. This means that the product is the result of intended chemical reactions.
- All impurities have been assayed and identified by the registrant. The registrant has not declared any 2. impurities of toxicological concern in this product. All impurities have a nominal concentration and upper certified limits.
- 3. The nominal concentration of the active ingredient listed on the proposed CSF and the draft label are the same.
- The draft label contains the appropriate storage and disposal statements. 4.
- 5. The active ingredient's certified limits as proposed on the basic CSF are acceptable.

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CONCLUSIONS:

CITAB has reviewed this submission and concludes the following:

 The basic formula CSF for the proposed manufacturing use product, Propanil Technical dated 30 Jan 2014 is acceptable.

- This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.330, 158.340, 158.345, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of formulation process, discussion of formation of impurities, certified limits, and enforcement analytical method.
- 3. This submission satisfies the data requirements as specified in 40 CFR 158.310 with respect to physical and chemical properties except for storage stability and corrosion characteristics. The registrant states that studies are in progress to satisfy the data requirements for the storage stability and corrosion characteristics.
- This product has been determined to be substantially similar in composition to EPA Reg. No. 71085-1 Riceco Propanil Technical from a product chemistry standpoint only.

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830.1550. Product Identity & Composition:

Common Name: Propanil

Chemical Name: 3,4-dichloropropananilide

CAS No.: 709-98-8

PC Code No.: 028201

Empirical formula: C₉ H₉ Cl₂ N O

Molecular Weight: 218.1

Structural formula:

PROPANIL

Manufacturing process information may be entitled to confidential treatment

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GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and Composition	493099-01	A	The NC of AI (98.50%) is supported by 5 batch analysis & agrees with the label claim NC. impurities (≥ 0.1%) are listed on the CSF
8301600	Description of Materials Used to Produce the Product	493099-01	A	The product specification sheets (MSDS) for all the starting materials have been provided by the registrant
830.1620	Description of Production Process	493099-01	A	been described in full detail. The reaction conditions, amounts of chemicals in each step, duration of time, and the yields in each step have been provided. The QA steps involved in each step have been described.
830.1670	Discussion of Formation of Impurities	493099-01	A	The registrant has provided the complete mechanisms of formation, quantification and identification of all the impurities present at the levels of ≥ 0.1%. Total of impurities have been listed on the CSF including No toxic impurity was reported during the synthesis.
830.1700	Preliminary Analysis	493099-01	A	The registrant has provided the analysis for terbatches of the active ingredient. The active ingredient and impurities were identified and quantified using gas chromatography with flame ionization detection. The methods were validated for accuracy, linearity, and precision. The active ingredient and impurities were identified by mass spectroscopy (MS). The LOQ and LOD for the active ingredient and each impurity were determined. The five batch analysis supported the CSF for basic formulation.
830.1750	Certified Limits	see basic csf 1/30/14	A	The proposed certified limits for the AI & for the impurities are based on the five batch analytical results.
830.1800	Enforcement Analytical Method	493099-01	A	The active ingredient and impurities were determined by gas chromatography using flame ionization detection (GC/FID). The method was validated for accuracy, precision and linearity.

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830 Series Subgroup B (Physical-Chemical Properties)

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	493099-02	Α	Gray
830.6303	Physical state	493099-02	Α	Amorphous solid
830.6304	Odor	493099-02	Α	Naphthalene-like odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	493099-02	A	The active ingredient stable when exposed to normal and elevated temperatures. The active ingredient was also stable when metals and metal ions.
830.6314	Oxidation/reduction: chemical incompatibility	493099-02	Α	Compatible with oxidizing & reducing agents, water, ammonium phosphate, iron powder, and potassium permanganate.
830.6315	Flammability		NA	Product is an amorphous sold.
830.6316	Explodability		NA	Product does not contain explosive components
830.6317	Storage stability		1	Study in progress
830.6320	Corrosion characteristics		1	Study in progress
830.7000	pH	493099-02	Α	6.27
830.7050	UV/Visible absorption	493099-02	A	pH A _{MAX} neutral 210 nm 20478 acidic 210nm 21044 basic 249nm 21772
830.7100	Viscosity		NA	Active ingredient is an amorphous solid.
830.7200	Melting point	493099-02	A	92.9°C
830.7220	Boiling point		NA	Active ingredient is an amorphous solid.
830.7300	Density	493099-02	Α	0.643 g/ml (pour) 0.728 g/ml (tap)
830.7370	Dissociation constants in water	493099-02	Α	pKa = 6.28 pI = 7.62
830.7550	Partition coefficient	493099-02	Α	Log P = 1.094
830.7840	Water solubility:	493099-02	A	Water - 0.132 g/ml @ 23°C Methanol - 663.3 g/ml @ 23°C Hexane – 0.427 g/ml @ 23°C n-Octanol – 381.728 g/ml @ 23°C
830.7950	Vapor pressure		NA	Product is an amorphous solid.

Y = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required

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CONFIDENTIAL APPENDIX

